

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

UNITED STATES OF AMERICA

v.

LAUREN STEVENS,

Defendant

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CRIMINAL NO. RWT-10-0694

**UNITED STATES' MOTION IN LIMINE AND
NOTICE OF POTENTIAL EVIDENTIARY ISSUES**

The United States of America hereby moves in limine to exclude certain potential categories of evidence and to give notice to the Court of certain potential evidentiary issues. The United States has discussed some of these issues with the defendant. It is not clear at this time whether the defendant will seek to introduce evidence in these categories. Pursuant to Federal Rule of Criminal Procedure 12(b)(3)(C), the United States is identifying potential evidence that it moves to exclude and is raising additional evidentiary issues that might require the Court's ruling.

Potential Evidence the United States Moves to Exclude

The United States moves to exclude from trial all argument and evidence, including both testimony and documents, on the following matters:

1. That the government did not indict other individuals. Argument or evidence that others involved in the response to the FDA's inquiry should have been indicted but were not – or that, because others were not prosecuted, the defendant should not be prosecuted or found guilty – is improper. It is not relevant to the defendant's guilt or innocence, *see* Fed. R. Evid.

402, and is likely to confuse, mislead, or sidetrack the jury, *see Fed. R. Evid. 403*. It is widely recognized that “[i]n our criminal justice system, the Government retains ‘broad discretion’ as to whom to prosecute.” *Wayte v. United States*, 470 U.S. 598, 607 (1985) (quoting *United States v. Goodwin*, 457 U.S. 368, 380 n.11 (1982)). The government also has the concomitant ability to decide whom *not* to prosecute. *McCleskey v. Kemp*, 481 U.S. 279, 311 (1987). Among the many reasons frequently cited for granting such broad discretion is the need to maintain prosecutorial flexibility in order to serve justice and advance important criminal policy goals. *See id.*; *Goodwin*, 457 U.S. at 380 n.11. Charging decisions against other potential defendants are, if anything, an expression of the prosecutor’s opinion and should not be used as evidence of the guilt or innocence of the defendant. *See Leonard B. Sand et al., Modern Federal Jury Instructions-Criminal* § 3.04 (2010) (“You may not draw any inference, favorable or unfavorable, towards the government or the defendants on trial, from the fact that certain persons were not named as defendants in the indictment Whether a person should be . . . indicted as a defendant is a matter within the sole discretion of the United States Attorney and the grand jury. Therefore, you may not consider it in any way in reaching your verdict as to the defendants on trial.”).

2. Any potential punishment or collateral impact to which the defendant may be subject if she is convicted. Argument or evidence that a conviction could result in a prison sentence or that the obstruction charges carry a statutory maximum of twenty years in prison, for example, is irrelevant, *see Fed. R. Evid. 402*, and carries the risk of unfair prejudice, *see Fed. R. Evid. 403*. The Supreme Court has held that “[i]t is well established that when a jury has no sentencing function, it should be admonished to reach its verdict without regard to what sentence

might be imposed.” *Shannon v. United States*, 512 U.S. 573, 579 (1994); *see also* Leonard B. Sand et al., *Modern Federal Jury Instructions-Criminal* § 9.01 (2010) (“The question of possible punishment of the defendant is of no concern to the jury and should not, in any sense, enter into or influence your deliberations. The duty of imposing sentence rests exclusively upon the court. Your function is to weigh the evidence in the case and to determine whether or not the defendant is guilty beyond a reasonable doubt, solely upon the basis of such evidence. Under your oath as jurors, you cannot allow a consideration of the punishment which may be imposed upon the defendant, if [she] is convicted, to influence your verdict, in any way, or, in any sense, enter into your deliberations.”).

3. Any consequences the defendant may have suffered as a result of being indicted or, prior to indictment, as a result of being identified as a target of a federal criminal investigation. Similar to the previous category, argument or evidence to the effect that the defendant “already has been punished enough” would be irrelevant, *see* Fed. R. Evid. 402, and inflammatory, *see* Fed. R. Evid. 403.

4. References in opening, closing, or otherwise to personal facts of the defendant’s life (including identification of family members in the courtroom) unless a witness will testify to such facts. Such evidence is not relevant to the defendant’s guilt or innocence, Fed. R. Evid. 402, or should be excluded because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, or misleading the jury, Fed. R. Evid. 403. Unless personal facts are admitted as evidence, counsel should not be allowed to reference them. *See United States v. Stockton*, 349 F.3d 755, 763 n.3 (4th Cir. 2003) (explaining counsel’s duty to not “inject into the case evidence not before the jury”); *United States v. Wilson*, 135 F.3d 291, 298 (4th Cir. 1998) (holding that closing argument must be “based on record

evidence”).

5. Other good acts and/or prior truthfulness of the defendant, except as admissible under Federal Rule of Evidence 404(a)(1) or 608(a). Defense counsel has indicated that he will be calling character witnesses. Such testimony should be limited to the defendant’s “pertinent” character traits, *see* Fed. R. Evid. 404(a)(1), and to her “character for truthfulness or untruthfulness,” *see* Fed. R. Evid. 608(a), in the form of reputation or opinion testimony, *see* Fed. R. Evid. 405. Testimony about non-pertinent character traits is inadmissible under Rules 404(a)(1) and 608(a), is irrelevant under Rule 402, and should further be barred by Rule 403. *Cf. United States v. Santana-Camacho*, 931 F.2d 966, 968 (1st Cir. 1991) (upholding exclusion of evidence that defendant “is kind or a good family man” in a human trafficking trial because such evidence did not speak to a pertinent character trait, was irrelevant, and was unduly prejudicial); *United States v. Nazzaro*, 889 F.2d 1158, 1168 (1st Cir. 1989) (affirming exclusion of evidence of a defendant police officer’s prior commendations because “the traits which they purport to show – bravery, attention to duty, perhaps community spirit – were hardly ‘pertinent’ to [perjury] of which [the defendant] stood accused”). Specific incidents of past conduct, including prior instances of truthfulness and other good acts, are also inadmissible on the grounds of Rules 402, 403, and 405(b). *See generally* 2 Jack B. Weinstein & Margaret A. Berger, *Weinstein’s Federal Evidence*, § 405.05 (2d ed. 1997) (“[T]here is no exception permitting a defendant to prove good character by specific acts.”)

6. Alleged corrective actions taken by the defendant after receipt of the letter from the Food and Drug Administration (“FDA”), except as such actions demonstrate knowledge of off-label promotion, are otherwise intertwined with relevant evidence, or are reflected in the letters. Such evidence is not relevant to the defendant’s guilt or innocence, *see*

Fed. R. Evid. 402, or should be excluded because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, or misleading the jury, *see* Fed. R. Evid. 403. It would also be inadmissible as a means to prove the defendant's character. *See* Fed. R. Evid. 405(b) (restricting the introduction of specific instances of conduct as evidence of a person's character).

7. That the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") took no formal action against the defendant or GSK. The government's position as to the irrelevance of such information was set forth in detail in its Opposition to Defendant's Motion to Compel, filed under seal on February 25, 2011 (DE 50). Furthermore, the Supreme Court has recognized that the FDA has complete discretion in administering the Food, Drug, and Cosmetic Act. *See Heckler v. Chaney*, 470 U.S. 821, 835 (1985). Any enforcement decision falls within that discretion, and whether the FDA chose to exercise that discretion is irrelevant to whether the defendant made false statements and obstructed a federal investigation.

8. Why the FDA did not meet with the defendant after her May 21, 2003 letter, why the FDA did not further respond to the defendant's requests for a meeting after her May 21, 2003 letter, or communications between the FDA and the Department of Justice regarding the Department's opening of an investigation. The government's position as to the irrelevance of such information was set forth in detail in its Opposition to Defendant's Motion to Compel, filed under seal on February 25, 2011 (DE 50). Argument and evidence on this point should be excluded under Rules 402 and 403.

9. That GSK ultimately produced documents, including the doctors' slide sets, in response to subpoenas issued as part of the Department of Justice investigation. The

indictment alleges that the defendant withheld from the FDA materials showing GSK's off-label promotion of Wellbutrin, such as slide sets used by GSK-paid doctor-speakers. Particularly in the context of the 18 U.S.C. § 1519 charge, the defendant may wish to argue that the defendant did not destroy the slide sets. At trial it will be self-evident that such materials were not destroyed and ultimately came into the government's possession. Aside from the possible need to explain in a neutral fashion that there was a time when the government did not have the materials, argument and evidence regarding how the government obtained these materials – years after the time period of the charged conduct – is irrelevant, *see Fed. R. Evid. 402*, and likely to confuse, mislead, and waste the jury's time, *see Fed. R. Evid. 403*.

10. The alleged percentage of off-label sales of Wellbutrin for weight loss or the treatment of obesity. The defense may wish to introduce evidence purporting to show that the percentage of Wellbutrin prescriptions for weight loss or the treatment of obesity is very low. At the time of the events in question, Wellbutrin was approved solely for the treatment of depression in adults. The FDA had not approved prescribing Wellbutrin as an "add-on" medicine to counteract the side effects suffered by depressed patients who already were being treated with another antidepressant. The defendant's own letters to physicians at the time acknowledged that promoting Wellbutrin for such "add-on" use was improper. There is a significant question about whether statistics regarding the use for which Wellbutrin was prescribed are accurate (i.e., whether an off-label Wellbutrin prescription to a depressed patient who already was being treated with another antidepressant would be categorized as a prescription for depression or a prescription for weight loss). Furthermore, a company which illegally promotes a product off-label violates the Food, Drug, and Cosmetic Act regardless of whether its efforts are successful. Therefore, the percentage of patients who were prescribed Wellbutrin for the off-label purpose of

weight loss or treating obesity is irrelevant.

11. Alleged evidence demonstrating that Wellbutrin is safe and effective for off-label uses. Such evidence is not relevant to the defendant's guilt or innocence, *see Fed. R. Evid. 402*, or should be excluded because any probative value is substantially outweighed by the danger of unfair prejudice, confusing the issues, or misleading the jury, *see Fed. R. Evid. 403*.

12. That the defendant was invited to speak at conferences regarding compliance with food and drug laws and/or was commended for her participation in such events by FDA employees or former FDA employees. Such evidence is not relevant to the defendant's guilt or innocence, particularly when her alleged misconduct was not made public until the indictment in this case was handed down on November 8, 2010, and thus should be suppressed under Rules 402 and 403.

13. The defendant's own out-of-court statements when offered by the defendant. The Court should exclude prior statements made by the defendant that the defendant attempts to introduce through (1) witnesses called by the government, (2) the defendant herself, or (3) any other witnesses called by the defense. The government intends to introduce into evidence the defendant's own statements through her own notes and the notes and testimony of others. Such statements are admissions of a party-opponent and therefore not hearsay. *Fed. R. Evid. 801(d)(2)(A)*. However, to the extent the defendant seeks admission of her own statements, the statements constitute inadmissible hearsay. *See id.*; *see also United States v. Milstein*, 401 F.3d 53, 73 (2d Cir. 2005) (ruling in the Rule 801(d)(2)(E) context that, to be admissible under Rule 801(d)(2), prior statements must be offered *against* the declarant or the declarant's conspirator). Prior statements by the defendant also are not admissible under Rule 801(d)(1)(B), which allows the admission of prior statements "to rebut an express or implied charge against the declarant of

recent fabrication.” Prior consistent statements by a witness “may not be admitted to counter all forms of impeachment or to bolster the witness merely because she has been discredited. . . . The Rule speaks of a party rebutting an alleged motive, not bolstering the veracity of the story told.” *Tome v. United States*, 513 U.S. 150, 157-58 (1995). Therefore, unless there are non-hearsay grounds for admission of a particular statement, the defendant’s own prior statements should be excluded.

Potential Evidentiary Issues

The United States also notes the following issues that may arise at trial and, in the interests of streamlining the trial and not using time for arguments once a jury has been impaneled, requests the Court’s guidance or, if necessary, rulings on how these issues should be handled¹:

A. Handwritten notes: The defendant, other attorneys, and paralegals took a large volume of handwritten notes during the course of GSK’s response to the FDA’s inquiry. These notes fall into several categories:

1. The defendant’s handwritten notes: The government understands that the parties agree that Stevens’ own notes are admissible in their entirety under Rule 801(d)(2)(A). The government is in the process of preparing these notes as an exhibit (or exhibits) that – like the other exhibits – will be presented electronically in the courtroom. The government anticipates that it will seek to have portions of these notes read to the jury by a summary witness or other witnesses.

2. Handwritten notes of individuals who are called as witnesses: Notes taken

¹The government is raising one additional potential evidentiary issue in a separate, sealed pleading.

by witnesses who are called to testify are likely admissible under Federal Rule of Evidence 803(1) (present sense impression), Rule 803(5) (recorded recollection), and/or Rule 803(6) (business records). Some of the notes also are likely admissible to show notice to the defendant and as evidence of the defendant's state of mind (i.e., they would not be offered for the truth of the matter asserted), provided the foundation has been laid that the statements were made in the defendant's presence. It may facilitate the presentation of these notes to address in advance whether the actual notes can be admitted or only read to the jury pursuant to Rule 803(5).

3. Handwritten notes of individuals who are not called as witnesses: These documents are not agreed to by either party as admissible, except as they may exist on a document otherwise admissible as having been sent by or received by Stevens and/or relevant to her state of mind.

B. Proffer: The defendant gave two proffers to the government in 2008. The proffer agreement provided that no statements made or other information provided by Stevens during those meetings could be used against her by the government "except for purposes of cross-examination and/or impeachment should she offer in any proceeding statements or information different from statements made or information provided by her during the proffer." Proffer agreements are enforceable according to their terms. *United States v. Lopez*, 219 F.3d 343, 346 (4th Cir. 2000) (noting proffer agreements should be interpreted akin to other contracts). *See generally United States v. Nesbitt*, No. 2:08-CR-1153-DCN, 2010 WL 3701337, at *5 (D.S.C. Sept. 14, 2010) (unpublished) (surveying cases). Furthermore, a defendant can breach a proffer agreement not only through her own words, but also through the arguments that her counsel offers and the statements of witnesses whom she presents. *See, e.g., United States v. Hardwick*, 544 F.3d 565, 571 (3d Cir. 2008) (holding that defense counsel's arguments, which were

inconsistent with the defendant's proffer, provided valid grounds for the introduction of proffer testimony); *United States v. Krilich*, 159 F.3d 1020, 1025 (7th Cir. 1998) (Posner, J.) ("This [proffer] agreement allowed the prosecutor to use the proffer as evidence if [the defendant] were to 'testify contrary to the substance of the proffer or otherwise present a position inconsistent with the proffer.' Introduction of the statements thus was proper if either his testimony or evidence that he presented through the testimony of others contradicted the proffer." (internal citations omitted)). Thus, should Stevens or her counsel make arguments or present evidence at trial that is inconsistent with what she said during her proffers, the government will be free for purposes of cross-examination and impeachment to use any conflicting statements that she made during her proffers.

Dated: March 4, 2011

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on March 4, 2011, a copy of the foregoing United States' Motion in Limine and Notice of Potential Evidentiary Issues was electronically filed with the Court and served on defense counsel listed below via ECF:

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